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Alerts & Publications

The Health Care Reform Legislation and its Impact on the Health Care and Life Sciences Industries

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On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (the "Act"), bringing sweeping and historic changes to the health care and life sciences industries.

The Act will require most Americans to have health insurance, expand Medicaid and establish a series of state-run exchanges through which individuals, families and small businesses can purchase health insurance meeting minimum standards to be defined by the federal government. The Act imposes new regulations on insurers that offer individual or small group coverage, even before the exchanges are established. The Act also contains several provisions that experiment with new payment models, which may lead to additional changes in the health care delivery system.

Every sector of the health care and life sciences industries can anticipate significant changes resulting from the Act. Over the next several weeks, O'Melveny will issue a series of client alerts that will analyze particular portions of the Act, the Act's impact on specific sectors of the health care and life sciences industries and the Act's impact on employers. This client alert is designed to summarize the key changes the legislation accomplishes and the high-level impact of those changes on the major segments of the health care and life sciences industries, including: Health Plans and the Managed Care Sector; Pharmaceuticals, Biologics, and Medical Device Companies; and Health Care Providers. The alert also analyzes provisions designed to curb fraud, abuse, and waste, and provides a roadmap of potential future developments.

Health Plans and the Managed Care Sector

The Act will have the most sweeping effects on the business models of the insurance and managed care sectors. In the short term, the legislation requires insurers to change certain underwriting practices and benefit structures. The same requirements apply to self-funded health plans. For instance, the Act requires insurers to take on children with pre-existing conditions, eliminates the ability to rescind coverage except in the most extreme circumstances, prohibits caps on lifetime benefits, and allows young adults to stay on their parents' insurance coverage until their 27th birthday. These initial reforms are likely to lead to premium increases as insurers and health plans absorb the costs of adding new individuals (many of whom will have higher than expected medical costs) to their coverage base and of changing their benefit structures. Until 2014, when the state-run exchanges go live, insurers will also be required to rebate to insureds any premiums devoted to

non-claim costs exceeding 20% for group insurance and 25% for individual policies.
The Act also imposes a series of broader changes beginning in 2014. Insurers likely will gain additional customers when the insurance mandate takes effect, requiring that most Americans obtain health coverage or face penalties. These new customers will have the option to purchase health insurance through a series of state-run exchanges that will offer health benefits packages meeting federal and state standards. The Act establishes certain community rating rules and limits insurers' ability to underwrite individual health insurance policies to specific factors: family structure (e.g., whether the plan covers an individual or family), rating area (which are established by individual states), age and tobacco use. The Act limits the allowable range of premium variation associated with even these few permitted underwriting considerations.

One of the critical components of the new reforms is the individual mandate to obtain coverage. If the penalties for failing to purchase coverage are effective in inducing participation, then the coverage mandate should help insurers at least partially mediate the loss of underwriting discretion by adding new healthy customers to their rolls. However, one of the most disputed points in the debate over the Act was whether the penalties for failing to purchase coverage are high enough to induce people who do not currently have health insurance — particularly those who are young and healthy — to purchase coverage.

The Act also imposes a flat fee of $6.7 billion across the health insurance industry over 10 years allocated across the industry based on a ratio, which is calculated from an insurer’s market share.

The long-term impact of this legislation on the managed care sector will depend on several factors, including:

- The outcome of litigation filed by several state attorneys general immediately following President Obama’s signing of the bill, which challenges the constitutionality of the individual mandate, may significantly impact the industry and the Act’s effectiveness. Their challenge contends that Congress lacks the authority under the interstate commerce clause to require individuals to buy health insurance; that the penalty for those who do not buy health insurance violates the Constitution’s tax-apportionment clause; and that the legislation violates the 10th Amendment by granting the federal government new powers. If the challenge is successful and the individual mandate is struck down, it would eviscerate the economic balance on which the reforms are purportedly based, putting insurers in the untenable position of being forced to cover additional unhealthy customers on a community rating basis without receiving the offsetting benefit of a group of new, healthy customers being forced into the system.
- Even if the state attorneys general challenges are unsuccessful, there are significant questions concerning whether the penalties underlying the mandate will prove sufficiently large to encourage healthy Americans to purchase insurance and whether there will be adequate enforcement mechanisms in place for those who do not comply.
- The details of the insurance exchanges will need to be worked out by federal and state regulators. The uncertainty concerning the operational details of the exchanges, including the minimum benefit packages, as well as the prospect for heightened regulatory scrutiny, will create pressure points within the managed care sector.

As the insurance and managed care sector responds to these reforms, insurers will likely seek to increase geographic reach in an effort to become more desirable to the state insurance exchanges. This may drive consolidation in the sector.

Finally, insurers that manage Medicaid or Medicare business will also be affected by the Act. The Act expands the Medicaid program to additional lower income persons. Medicaid managed care plans will likely benefit from this expansion. On the other hand, Medicare insurers, known as Medicare Advantage plans, will see sharp cuts in reimbursement, which may require plans to trim supplemental benefit offerings and increase premiums. These cuts may make it more difficult for insurers to demonstrate to beneficiaries a "value proposition" vis-à-vis traditional fee-for-service Medicare and could put pressure on their enrollment figures.

Pharmaceuticals, Biologics, and Medical Devices

The Act should provide a boost to elements of the life sciences industry. Pharmaceutical companies, for example, should see an increase in revenue as more people will have insurance to pay for drug coverage. This will come at a price: The Act requires drug companies to contribute more than $80 billion toward the cost of reform in the form of industry fees and a 50 percent discount to Medicare beneficiaries for drugs purchased in what is known as the "donut hole," the gap in a Medicare beneficiary's drug benefit that exists after the initial drug benefit but before the member reaches Medicare's catastrophic coverage. Over time, the legislative package will close the "donut hole," which has resulted in some Medicare patients not filling prescriptions because they were unable to pay for them.

Biotechnology companies should also see benefits under the Act. For example, the Act bestows upon the high-growth biotechnology sector a new 12-year window of protection from generic competition, providing additional incentive for continued product development and investment in the industry.

The Act also imposes new transparency requirements on the life sciences industry. Under the Act, effective beginning April 2013, pharmaceutical, biotechnology and medical device manufacturers must report payments and other things of value provided to certain providers, including doctors, medical practices, and teaching hospitals. The Act also requires increased transparency in price concessions offered to certain pharmacy benefit managers. Pharmacy benefit managers will see increased reporting requirements related to rebates and discounts received from pharmaceutical companies as well as reporting regarding the pharmacy benefit manager's generic dispensing rates and supply chain pricing.

Health Care Providers

The Act appears likely to have a mixed effect on providers. On the one hand, over the long haul, the Act will give providers additional paying patients that should ease write-offs attributable to providing care to uninsured patients. For example, when the insurance mandate takes effect in 2014, hospitals should see a reduction in the number of uninsureds seeking primary health care

services in the emergency room, where the cost of care is generally very high. On the other hand, the Act leaves several unanswered questions concerning the direction of per-unit reimbursement rates and the overall direction of health care payment models.

Providers will see an increase in public and private payors attempting to link payment with quality and outcomes. The Act, for instance, establishes a value-based purchasing program for hospitals that will launch in 2013, and will begin to link Medicare payments to the quality of patient care. The Act also establishes demonstration projects for new patient care models, encouraging hospitals, doctors, and post-acute providers, like skilled nursing facilities and physical therapy providers, to integrate their services to improve patient care and achieve savings through bundled payments. More generally, the prospect of emerging reimbursement models may drive providers to adopt new health delivery models. This could lead to increased activity in strategic mergers and acquisitions, as the more adaptive providers acquire the infrastructure necessary to support delivery models

Fraud and Abuse

A lesser-known yet significant aspect of the Act is aimed at reducing fraud, waste and abuse in the health care and life sciences industries. The Act contains several provisions that appropriate significant funds and dedicate considerable resources to fraud and abuse enforcement. These provisions also increase transparency into industry practices and modify certain substantive laws — such as the False Claims Act and the Anti-Kickback Statute — to make it easier for the government and private plaintiffs to bring and sustain a case against a health care or life sciences company.

These changes are in line with other recent amendments to federal health care fraud and abuse laws. For example, substantial changes to the federal privacy law were instituted by the Stimulus Act, known as the American Recovery and Reinvestment Act, and liability under the False Claims Act was expanded as part of the Fraud Enforcement and Recovery Act of 2009.

Not surprisingly, the President's most recent budget and the Act dedicate significant resources to health care fraud enforcement. Specifically, the President's proposed budget sets aside $1.7 billion, and the reform package provides an additional $350 million over the next ten years, to fund a number of enforcement agencies tasked with fighting health care fraud, including the U.S. Department of Health and Human Services' Office of Inspector General and the U.S. Department of Justice.

The Act also modifies several key substantive laws, thereby removing a number of substantive obstacles in the path of these enforcement agencies and private plaintiffs, including whistleblowers under the False Claims Act. For example, the Act modifies the False Claims Act's "original source rule," which historically has served a gate-keeping function against whistleblowers that have sought to bring cases based upon publicly disclosed information. The question of whether such a whistleblower's case should proceed is now vested in the Department of Justice, which may well expand the number and types of cases brought by whistleblowers. The Act also requires the report and return of Medicare and Medicaid overpayments within 60 days of identification. With these changes, a knowing failure to report and return an overpayment can now lead to liability under the False Claims Act.

The Act also modifies the Anti-Kickback Statute. It clarifies that a showing of specific intent is not necessary under the statute, thereby attempting to eliminate the heightened *scienter* requirement imposed by at least one Federal Circuit. The Act also codifies several federal judicial opinions that held that claims resulting from kickback arrangements constitute "false or fraudulent claims" under the False Claims Act. These changes to the False Claims Act and the Anti-Kickback Statute are but two examples of the changes the Act brings to federal anti-fraud laws.

Taken together, the Act and other recent legislative changes (including changes to the Medicare secondary payor laws) leave the government and the plaintiff's bar well-poised to levy a broad, renewed attack on the health care and life sciences industries. These changes likely will meaningfully alter the health care fraud enforcement landscape as the government seeks to pay for the hefty price tag associated with implementing the Act's reforms.

The Road Ahead

The passage of the Act marks a watershed moment for the health care and life sciences industries. The Act's actual effect on the industry, however, will be determined by the manner in which the Act is implemented and the manner in which industry responds. The Act leaves many crucial details, including operational details concerning state-run exchanges, in the hands of federal and state regulators. In addition, as mentioned, several states already have challenged the Act's constitutionality, and, with congressional elections fast approaching this fall — and a Presidential election only three years away — Republicans have already started exploring avenues to repeal the legislation. By contrast, many groups view the current Act as merely a starting point to advance additional reforms within the industry — including the possibility of a public option, more market-based reforms of the health care purchasing process and more rigorous cost-control measures.